

REMARKS

Claims 5, 9-10, 12-14 and 80 are pending. Claims 10, 12, 14 and 80 have been amended herein. No new matter has been added.

Priority

The Examiner has requested that Applicants provide the serial number of any parent application to which priority is desired which specifically supports the particular claims. Applicants respectfully submit that the pending claims are supported by provisional application U.S.S.N. 60/182,724, filed February 15, 2000, in its entirety.

Title

The Examiner has stated that the Title is not descriptive. The title has been amended here in to "Novel GAGE-like Proteins and Nucleic Acids Encoding Same".

Correction of Inventorship

Applicants respectfully point out that a Petition and Amendment to Correct Inventorship was filed February 3, 2004 (copy attached hereto).

Rejections under 35 U.S.C. §101

Claims 5, 9-10, 12-14, and 80 are rejected under 35 U.S.C. §101 as the Examiner contends that the claimed invention is not supported by either a credible, specific and substantial asserted utility or a well-established utility.

Applicant respectfully disagrees. Under 35 U.S.C. §101, what is required is the assertion of a utility that is specific, substantial and credible. Applicant has asserted such a utility for the claimed invention in the specification. For example, the specification states that NOV2 can be used to detect prostate tissue, for diagnostic or therapeutic uses in association with melanoma (page 11, lines 6-14). One of skill in the art could follow the teachings of the specification, such as Example 8 beginning at page 129 to assess the quantitative differential expression of NOV2 genes in normal and pathological tissues by RTQ-PCR. Applicant has taught that differential expression is expected in melanoma cancer tissue. One of skill in the art, having read the

specification, would therefore know to detect and compare the level of expression of the nucleotide encoding SEQ ID NO:4 in samples of melanoma by using, e.g. RTQ-PCR methods as described specifically in the specification to differentiate malignant from normal tissues.

The utility described above is specific. Applicant has not suggested that NOV2 be used in a general undefined way or for diagnosing an unspecified disease. The specification does not teach that NOV2 be used the presence of any human tissue. The specification teaches that the nucleic acid encoding the polypeptide of SEQ ID NO:4 may be used as a specific target for detecting expression, particularly in melanoma, to differentiate normal tissue from malignant tissue. This is a specific utility. Furthermore, the specification teaches that not any nucleic acid but specifically NOV2 may be used for this purpose.

The utility described above is substantial and defines a real world use. A specific assay is described e.g. RTQ-PCR which detects differential gene expression, specifically in diseased tissues and provides results that can be used to differentiate malignant from normal tissue. Applicant's stated utility is not basic research, a method of treating an unspecified disease, a method of assaying for a material of no specific utility, a probe with no information as to what the probes are for, or the like. Applicant's stated utility is substantial and applicant respectfully submits that further experimentation is not required to recognize the utility of the NOV2 gene for differentiating specific malignant from normal tissues.

Applicants respectfully point out that Applicant's teaching has in fact been born out. PCT/US02/09808 (copy attached) discloses RTQ-PCR results detecting Hs.293317 (which is the same as NOV2 of the present application) in normal and malignant tissues and specifically demonstrates differential expression in 9/18 melanoma tissues (see page 74-75, particularly Table 5).

Since the applicant has made an assertion that the claimed invention is useful for a particular purpose, and such assertion would be considered credible by a person of ordinary skill in the art, a rejection based on lack of utility is not proper. Applicant respectfully requests that the rejection under 35 U.S.C. §101 be withdrawn.

Rejections under 35 U.S.C. §112, first paragraph

Claims 5, 9-10, 12-14, 80 are rejected under 35 U.S.C. §112, first paragraph as the Examiner contends that the claimed invention is not supported by either a specific and

substantial asserted utility or a well established utility, one skilled in the art clearly would not know how to use the claimed invention.

Applicant respectfully disagrees. As described above NOV2 does have a specific, substantial and credible utility. One of skill in the art, having read the specification, would know to detect and compare the level of expression of the nucleotide encoding SEQ ID NO:4 in samples of melanoma by using, e.g. RTQ-PCR methods as described specifically in the specification to differentiate malignant from normal tissues. Applicant requests that the rejection of claims 5, 9-10, 12-14, 80 are rejected under 35 U.S.C. §112, first paragraph be withdrawn.

Claim 14 is rejected under 35 U.S.C. §112, first paragraph as the Examiner alleges that while the specification is enabling for a host cell in culture comprising a polynucleotide with the sequence as set for the in SEQ ID NO:3, it does not reasonably provide enablement for *in vivo* transfection. Claim 14 has been amended to recite "an isolated" cell. Applicant requests that this rejection be withdrawn.

Claim 80 is rejected under 35 U.S.C. §112, first paragraph as the Examiner contends that while the specification is enabling for a nucleic acid molecule encoding a polypeptide comprising an amino acid sequence set forth in SEQ ID NO:4, it does not reasonably provide enablement for a nucleic acid molecule comprising a complement of a nucleotide sequence encoding a polypeptide comprising an amino acid sequence set for the in SEQ ID NO:4. Claim 80 has been amended herein to pertain to the complement of the nucleic acid of claim 5. Applicant requests that this rejection be withdrawn

Rejections under 35 U.S.C. §112, second paragraph

Claims 10, 12-13, 80 are rejected under 35 U.S.C. §112, second paragraph as the Examiner contends the claims are indefinite for fail to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10, has been amended herein to specifically define stringent hybridization conditions as "comprising a high salt buffer comprising 6X SSC, 50 mM Tris-HCl (pH 7.5), 1 mM EDTA, 0.02% PVP, 0.02% Ficoll, 0.02% BSA, and 500 mg/ml denatured salmon sperm DNA at 65°C." Support for this amendment can be found in the specification at page 57, line 31

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to page 58, line 5. Furthermore the claim has been amended as suggested by the Examiner to a nucleic acid that hybridizes to the *complement* of SEQ ID NO:3. As such, Applicant believes claim 10 is definite and Applicant respectfully requests this rejection be withdrawn.

Claim 12 (and therefore dependent claim 13) has been amended to recite "a recombinant expression vector" as suggested by the Examiner. Support for this amendment can be found in the specification (page 85, lines 20-21). Applicant respectfully request this rejection be withdrawn.

Applicants have amended claim 80 herein to recite "nucleic acid molecule comprising a complement of the nucleotide sequence of claim 5" and thereby believe the claim is definite. Applicant respectfully request this rejection be withdrawn.

Rejections under 35 U.S.C. §102

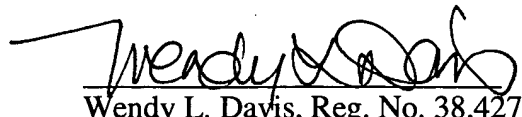
The Examiner has rejected claims (specific claim numbers unspecified) under 35 U.S.C. §102(a) and §102(e) as the Examiner contends the claims are anticipated by WO 01/61009, filing date 15 February 2001. As discussed above, the current invention claims priority to US provisional application U.S.S.N. 60/182,724, filed February 15, 2000 and therefore WO 01/61009 is not available as prior art under 35 U.S.C. §102(a) or §102(e). Applicant respectfully requests that this rejection be withdrawn.

CONCLUSION

Applicants respectfully request that the amendments and remarks made herein be entered and made of record in the file history of the present application. Applicants respectfully submit that this paper is fully responsive and that the pending claims are in condition for allowance. Such action is respectfully requested. If there are any questions regarding these amendments and remarks, the Examiner is encouraged to contact the undersigned at the telephone number provided below.

Respectfully submitted,

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